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K946281

510(k) SummaryEffectiveness

The pediatric enhancement to the interpretative program was developed by Dr. Peter MacFarlane in the University of Glasgow Department of Cardiology, Glasgow Royal Infirmary (GRI), Glasgow, Scotland. Dr. MacFarlane has been involved in computerized ECG interpretation since its inception in the 1960s. The GRI pediatric criteria is based on a large study of 2,196 neonates, infants and children.

The Burdick Eclipse 4 performs the same functions and meets the same performance standards as the Marquette MAC PC. This version of the Burdick GRI interpretative program and Marquette's interpretative program used in the MAC PC both provide adult and pediatric resting ECGs on patients ranging in age from birth to 99 years. Both programs analyze 10 seconds of data simultaneously from the 12 standard leads and identify essentially the same set of abnormalities.

Safety

The addition of pediatric interpretation does not change the analysis of potential risks as outlined in the Eclipse 4 510(k) submittal (# K943959) concerning electrical shock, misrepresentation of the patient's ECG, inability of the operator to successfully record an ECG, mechanical pinch points and device falling.

Burdick conducted a review of the literature pertaining to safety of pediatric interpretative capabilities in electrocardiographs. Appropriate safeguards have been incorporated in the design of the Eclipse 4.

The device labeling includes instructions for safe and effective use. It includes warnings, cautions, and guidance for installation and maintenance.